Notice of Allowability	Application No. 10/517,251	Applicant(s) HOGARTH ET AL.	
	Examiner Anne Marie S. Wehbe	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the after-final amendment received on 8/10/07*.

2. ☒ The allowed claim(s) is/are *1-3,5,8,9,11,12 and 43-52*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ATTACHMENT TO ALLOWANCE

Applicant's after-final amendment received on 8/10/07 has been entered. Claims 4, 6-7, 10, and 13-42 are canceled. Claims 1-3, 5- 8-9, and 11-12 were pending following entry of the after-final amendment.

Interviews

The applicant originally contacted the examiner to inquire after the after-final amendment filed on 8/10/07. The examiner determined that the document has not been entered into the PALM system and requested immediate entry of the document. The case was then forwarded to the examiner on 10/22/07. After consideration of the amendment, the examiner contacted the applicant's representative on 10/30/07 to discuss potential claim amendments to place the application in condition for allowance. The applicant's representative provided the examiner with a proposed draft amendment of the claims on 11/3/07. The examiner again contacted the applicant's representative on 11/5/07 to discuss the draft amendment. On 11/8/07, agreement was reached and the examiner agreed to make the amendments to the claims via examiner's amendment to place the application in condition for allowance.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Darla Yoerg on 11/8/07.

The application has been amended as follows:

1. Claim 1 has been rewritten as follows:

1. A method for screening a compound that is able to suppress aberrant immune activity, wherein the aberrant immune activity is selected from aberrant immune complex formation and immune complex induced inflammation, the method comprising the steps of:

a. administering a compound to be screened to a transgenic mouse generated by transgenically modifying an embryo from a strain, derived from strains C57BL/6 and SJL, that is resistant to collagen-induced arthritis, such that said mouse comprises and expresses a transgene for human FcγRIIa receptor, whereby the expression of said FcγRIIa receptor renders the mouse susceptible to spontaneous development of an autoimmune disease selected from the group consisting of arthritis and systemic lupus erythematosus; and

b. assessing the transgenic mouse to determine if the compound reduces said aberrant immune activity associated with arthritis or systemic lupus erythematosus in the mouse.

2. Claim 2 has been rewritten as follows:

2. A method for screening a compound that is able to suppress an autoimmune disease caused by aberrant immune activity by suppressing aberrant immune activity selected from aberrant immune complex formation and immune complex induced inflammation, the method comprising the steps of:

a. administering a compound to be screened to a transgenic mouse generated by transgenically modifying an embryo from a strain, derived from strains C57BL/6 and SJL, that is resistant to collagen-induced arthritis, such that said mouse comprises and expresses a transgene for human FcγRIIa receptor, whereby the expression of said FcγRIIa receptor renders the mouse susceptible to spontaneous development of an autoimmune disease selected from the group consisting of arthritis and systemic lupus erythematosus; and

b. assessing the transgenic mouse to determine if the compound reduces said aberrant immune activity associated with arthritis or systemic lupus erythematosus in the mouse.

3. Claim 3 has been rewritten as follows:

3. A method for screening a compound that is able to suppress an autoimmune disease caused by aberrant immune activity, the method comprising the steps of:

a. administering a compound to be screened to a non-human cell expressing human FcγRIIa receptor , wherein the cell is selected from the group consisting of platelets, neutrophils, and macrophages, and wherein the cell is derived from a transgenic mouse generated by transgenically modifying an embryo from a strain, derived from strains

C57BL/6 and SJL, that is resistant to collagen-induced arthritis, such that said mouse comprises and expresses a transgene for human FcγRIIa receptor, whereby the expression of said FcγRIIa receptor renders the mouse susceptible to spontaneous development of an autoimmune disease selected from the group consisting of arthritis and systemic lupus erythematosus; and

b. assessing the cell to determine if the compound reduces said aberrant immune activity associated with arthritis or systemic lupus erythematosus in the cell.

4. In claim 8, line 3, the word "rodent" has been replaced by the word - - mouse--.

5. In claim 9, line 3 the phrase "an autoimmune disease" has been replaced by - - arthritis or systemic lupus erythematosus - -.

6. New claims 43-52 have been added as follows:

43. A method according to claim 2, wherein the method comprises assessing the transgenic mouse to determine if the compound reduces immune complex induced inflammation.

44. A method according to claim 2, wherein the compound reduces aberrant immune activity in the transgenic mouse by inhibiting the activity of human FcγRIIa receptor expressed in the mouse.

45. A method according to claim 2, wherein in step (b) the aberrant immune activity is assessed in terms of clinical symptoms and/or pathological features of arthritis or systemic lupus erythematosus.

46. A method according to claim 2, wherein the autoimmune disease is rheumatoid arthritis (RA).

47. A method according to claim 2, wherein the autoimmune disease is collagen-induced arthritis (CIA).

48. A method according to claim 3, wherein the method comprises assessing the cell to determine if the compound reduces immune complex induced inflammation.

49. A method according to claim 3, wherein the compound reduces aberrant immune activity in the cell by inhibiting the activity of human FcγRIIa receptor expressed in the cell.

50. A method according to claim 3, wherein in step (b) the aberrant immune activity is assessed in terms of clinical symptoms and/or pathological features of arthritis or systemic lupus erythematosus.

51. A method according to claim 3, wherein the autoimmune disease is rheumatoid arthritis (RA).

52. A method according to claim 3, wherein the autoimmune disease is collagen-induced arthritis (CIA).

Following entry of this examiner's amendment, the rejections of the previously pending claims under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 103(a) have been withdrawn.

Claims 1-3, 5, 8-9, 11-12, and 43-52 are pending and allowed.

The following is an examiner's statement of reasons for allowance: the amendment the claims limiting the transgenic mouse to a strain derived from strains C57BL/6 and SJL overcomes the previously pending rejection of the claims under 35 U.S.C. 112, first paragraph, for scope of enablement. Further, the amendment of the claims to indicate that the transgenic mouse spontaneously develops arthritis and systemic lupus erythematosus and that the assessing step determines if the compound reduces aberrant immune activity associated with arthritis or systemic lupus erythematosus overcomes the rejection of the claims under 35 U.S.C. 103(a) based on the teachings of McKenzie et al. It is noted that while McKenzie et al. teaches a mouse with the same structure as that in the claims, McKenzie et al. only teaches assessing immune complex clearance associated with thrombocytopenia and does not teach or suggest assessing aberrant immune activity, and in particular aberrant immune complex formation and immune complex induced inflammation, associated with arthritis or systemic lupus erythematosus

because McKenzie et al. did not recognize that the transgenic mice spontaneously develop arthritis and systemic lupus erythematosus as they age. Therefore, neither McKenzie et al. nor remaining prior art of record provide teachings or motivation for using the transgenic mice or cells derived from the transgenic mouse as claimed to test for compounds capable of suppressing aberrant immune activity associated with arthritis or systemic lupus erythematosus.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

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Primary Examiner, A.U. 1633